

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4, 7-10, 13-15, 18, 19, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There does not appear to be support in the originally filed specification for the phrase "an edible concentrate comprising a fat base consisting essentially of a mixture of enzymatically-prepared vegetable-derived triglycerides" as Applicant's specification uses "comprising" language only, and the amended limitation of the concentrate requires "dilution" with complementary vegetable oils also does not appear to be supported in the originally filed specification. Furthermore, in amended Claim 18, there does not appear to be support in the originally filed specification for the unsaturated fatty acids "principally" including oleic acid. This is a new matter rejection and Applicant is encouraged to point out where support can be found for the amended claim limitation.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-4, 7-10, 13-15, 18, 19, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding amended Claim 1, the phrase "an edible concentrate comprising a fat base consisting essentially of a mixture of enzymatically-prepared vegetable-derived triglycerides" is unclear in light of Applicant's specification, where it is stated that the fat base composition is InFat, which is made of the enzymatically-prepared vegetable derived triglycerides, which is also referred to as the concentrate material (see Page 17, Paragraph 2 of Applicant's specification). Therefore, the claim appears to be claiming, InFat comprising InFat, consisting essentially of InFat, which is unclear.

6. Regarding amended Claim 18, it is unclear how much oleic acid would be necessary for the unsaturated fatty acids to "principally" include oleic acid, and the specification does not provide any further guidance on this issue. Therefore, the claim is indefinite.

***Claim Rejections - 35 USC § 102/ Claim Rejections - 35 USC § 103***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**11. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over “Food Ingredients First.com, July 4, 2003), previously made of record.**

12. Regarding Claims 1-4, the Food Ingredients First.com article teaches the enzymatically prepared fat base composition called InFat (see article, Page 1,

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Paragraphs 1-5), which applicant discloses is the fat base composition and concentrate claimed in Claims 1-4, (see instant specification, Page 11, Paragraph 5, and Page 12, Paragraph 3). The Food Ingredients First.com article teaches that InFat is an exclusive oil with a specific triglycerides' composition, designed to have a higher palmitic acid content at the correct position of the triglycerides and teaches that up to 90% of the total palmitic acid in InFat is located at the sn-2 position of the triglyceride and further teaches incorporating InFat into infant formulas and blending it with complementary oils (see article, Page 1, Paragraphs 1, 2 and 4), and also teaches that the new ingredient for infant formulas is said to be closer to the fat found in human milk, thus infant formula containing InFat would be deemed a substitute human milk fat composition. Since the article teaches the new fat ingredient InFat, it will have necessarily comprise the claimed saturated and unsaturated fatty acids in the claimed ranges or concentrations.

13. In the alternative, the claimed edible concentrate would have been obvious to one of ordinary skill in the art at the time that the invention was made, because since InFat is a trademark representing a fat composition or concentrate comprising a specific range of constituents, which is also being claimed by Applicant, it would have been reasonably expected to one of ordinary skill in the art that a teaching of InFat in the art would have comprised the specific fatty acid residues in amounts that would meet the claimed ranges or amounts.

***Claim Rejections - 35 USC § 103***

14. **Claims 1-4, 7-10, 13-15, 19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (U.S. Patent No. 4,876,107) in view of Innis et al. (American Institute of Nutrition, 1995), both previously made of record.**

15. Regarding Claims 1-4, 9 and 20, King teaches an edible concentrate comprising a fat base which includes a mixture of enzymatically-prepared vegetable derived triglycerides because King teaches a novel fat composition suitable for replacing at least a part of the fat in infant food formulations (Column 2, lines 20-25). King teaches that the novel fat composition results from the rearrangement of vegetable fat via enzymes (Column 3, lines 20-25), therefore reading on the fat base including enzymatically-rearranged vegetable derived triglycerides. Since King teaches mixing the fat base or novel fat composition with vegetable oils to prepare substitute milk products (Column 1, lines 5-10, Column 2, lines 45-55 and Column 6, Claims 6-8 ), King teaches the claimed edible concentrate.

16. King teaches that at (b) least 60% of fatty acid residues at an sn-2 position of a glycerol backbone are palmitic acid residues (Column 2, lines 25-30 and Table 1, Sample 3 which is the fat base concentrate, where 80% of the fatty acid residues at an sn-2 position are palmitic acid residues). King also teaches that (c) (i) 6-17% of the unsaturated fatty acid residues at the sn-1 and sn-3 positions are linoleic acid residues because King teaches in Table 1 Sample 3 11.7% linoleic acid residues out of the total unsaturated fatty acid residues at the sn-1 and sn-3 position. King also teaches at least 62% and up to 70% of the total palmitic acid residues of the mixture are at the sn-2

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position because King teaches 66.7% of the total palmitic acid residues of the mixture are at the sn-2 position (see Table 1, Sample 3,  $(80/3/40)*100=66.7\%$ ). King also teaches at least 70% of the fatty acid residues at the sn-1 and sn-3 positions are oleic acid and other unsaturated fatty acid residues (see Table 1, Sample 3, and 70% of the fatty acid residues at the sn-1 and sn-3 positions are oleic and other unsaturated fatty acid residues).

17. Regarding Claim 1, (a), King teaches a slightly higher than claimed amount of palmitic acid residues content of the mixture at 40% (Table 1, Sample 3), and therefore does not specifically teach that the palmitic acid residues are at most 38% of the total fatty acid residues.

18. Innis teaches that palmitic acid represents 20-30% of the fatty acids in human and pig milk, and around 70% of this is esterified to the sn-2 position of the milk triacylglycerol (Page 73, Column 1, lines 1-5). Innis further teaches that a higher fat absorption has been found in infants fed triacylglycerols with 16:0 esterified to sn-2 rather than sn-1,3 positions and on the basis of this finding, the higher coefficient of absorption of human milk fat has been hypothesized to be related to the positioning of 16:0 at the sn-2 position of the milk triacylglycerol (Page 73, Column 2, lines 12-19). Innis teaches that the results of the studies undertaken are consistent with the hypothesis that the preferential esterification of 16:0 at the sn-2 position of milk triacylglycerols is important to ensure a high coefficient of milk fat absorption (Page 79, Column 1, lines 22-28). Innis teaches that the present study confirms previous work which found that feeding milk or formula containing 55-70% 16:0 in fatty acids esterified

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to the triacylglycerol sn-2 position results in enrichment of plasma cholesteryl esters with 16:0 (Page 80, Column 1, lines 55-57).

19. Therefore, King teaches that it is known and beneficial to develop infant formulas that approximate the fatty acid profile of mother's milk in order to reproduce its physical and dietary characteristics and Innis teaches that palmitic acid represents 20-30% of the fatty acids in human milk. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, for the edible concentrate of King to have a slightly lower palmitic acid content, because King teaches the importance of developing infant formulas that possess a fatty acid profile that approximates mother's milk and Innis teaches that palmitic acid represents 20-30% of the fatty acids in human milk. Therefore, one of ordinary skill in the art would have been motivated by both King and Innis to develop a fat base composition for use in infant formulas that approximates, as close as possible, the total amount of palmitic acid in human milk and therefore slightly lower the amount of palmitic acid in the concentrate in order to provide a suitable substitute to human milk for infants that has the closest possible composition to human milk.

20. Regarding Claims 7-10, 14, 15, 19, 21 and 22, King in view of Innis teaches a substitute milk fat composition in the form of blends for use in feeding young mammals and especially infants (King, Column 1, lines 7-8) and teaches that an infant formula comprises a blend of the of a rearranged vegetable fat composition along with vegetable oil, such as sunflower oil or soya bean oil (King, Column 2, lines 5-55, Column 6, lines 50-21 and 45-46), and teaches a blend of 10-30% vegetable oil, 20%

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lauric fat, which can be palm kernel oil, which is also a vegetable oil in light of Applicant's Claim 8, and therefore 30-50% total vegetable oil is taught by King, and the balance would be the rearranged fat composition or edible concentrate in an amount of between 70-50% by weight. King in view of Innis teach that the resulting infant formula provides fat, protein and carbohydrate, where in the fat normally found in such formulations is replaced by an enzymatically rearranged fat in accordance with the present invention (see King, Column 3, lines 20-25).

21. Regarding Claim 13, King in view of Innis are taken as cited above in the rejection of Claims 7-10 above, and therefore also teaches a process for the preparation of a substitute human milk fat composition comprising admixing the vegetable oil with the edible concentrate.

**22. Claims 11, 12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (U.S. Patent No. 4,876,107) in view of Innis et al. (American Institute of Nutrition, 1995), and further in view of Cooper (U.S. Patent No. 5,371,253), all previously made of record.**

23. Regarding Claims 11, 12 and 18, King in view of Innis are relied upon as cited above in the rejection of Claim 1.

24. Regarding Claims 11 and 18, King in view of Innis are taken as cited above in the rejection of Claim 1 and teach a process of preparing an edible concentrate comprising the steps of: (a) reacting an upper-melting fraction of palm oil, which is expected to be rich in palmitic acid, with oleic acid, in the presence of lipase deposited on Celite (see



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King, Column 4, lines 51-55), which is deemed an insoluble catalyst in view of Applicant's disclosure and use of an immobilized lipase per Example 1 on Page 16 of Applicant's specification. It is noted that King also uses hexane in the process, but since Claim 11 claims "comprising the steps of", this does not preclude the use of other elements also present in the process. King in view of Innis further teach (b) removing the catalyst, and (c) distilling the free fatty acids (see King, Column 4, lines 62-68).

25. Regarding amended Claims 11 and 12, King in view of Innis do not specifically teach the step (d) of bleaching the oil after distilling and step (e) deodorization of the product of step (d), also do not specifically teach the step of fractionation preceding deodorization.

26. Cooper teaches that processing steps such as degumming, bleaching, filtration, deodorization, fractional crystallization, which is deemed to meet the limitation of a fractionation step, and the like are techniques known in the art for refining natural vegetable or animal oils and fats and that products produced from fatty acids, such as palm oil or palm kernel oil, can be additionally purified or treated using such techniques (Column 8, lines 64-68, Column 9, lines 1-3 and Column 10, lines 46-47 and 64-66).

27. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, for the process of preparing a fat base composition to have further comprised the step of bleaching, deodorization and a step of fractionation preceding deodorization, because Cooper teaches that bleaching, deodorization and fractionation are techniques known in the art for refining natural vegetable or animal oils and teaches such techniques can be used on products produced from palm oil or palm

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kernel oil. One of ordinary skill in the art would have been motivated by Cooper to use such known techniques as bleaching, deodorizing and fractionation for their known benefits in order to produce a more refined or treated final product.

28. Regarding the specific series of method steps in Claim 12, it has been found that “selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results.” See MPEP 2144.04 IV C. In the instant case, the selection of the order of the deodorization and fractionation steps after the step of bleaching would be expected to be obvious to one of ordinary skill in the art at the time that the invention was made, in order to efficiently and economically prepare a fat base composition of the desired purity and quality.

### ***Response to Arguments***

29. The 112 1<sup>st</sup> new matter rejection previously set forth in the office action mailed on 9/27/2010 has been withdrawn in light of Applicant's amendments.

30. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

31. Regarding Applicant's arguments relating to the reference of Innis, it is noted that Innis is used to motivate the claimed total amount of palmitic acid, for which Innis provides clear motivation and therefore, the claimed amount of at most 38% of the total fatty acid residues being palmitic acid residues would have been obvious to one of ordinary skill in the art in light of the teachings of Innis. Furthermore, absent a teaching of criticality in the claimed amount of palmitic acid, a slight decrease from 40% to at

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most 38% would not have been expected to amount to a patentable distinction for one of ordinary skill in the art, given the teaching in the art of an amount of palmitic acid that is known to be present in human milk fat that meets the claimed amount.

32. Furthermore, in light of the teachings of King and the prior art, modifying the fatty acid composition to be in the range claimed by Applicant would have been reasonably expected to be the result of routine experimentation to one of ordinary skill in the art for the reasons stated above.

33. Regarding Applicant's arguments relating to the rejection of the method claims 11, 12 and 18, it is again noted that King in view of Innis teach the bulk of the method steps and the remaining steps of bleaching, deodorization and fractionation are known steps to be carried out when dealing with purification of vegetable oils, as taught by Cooper, therefore, to incorporate such method steps into the method of King in view of Innis would have been obvious to one of ordinary skill in the art in view of the art recognized benefits of such steps. It is further noted that Applicant applies the same method steps for the same purposes as expressed in the art, namely using the method steps for their conventional and traditional functions.

34. Regarding the new 102/103 rejection of Claims 1-4 over the NPL reference article, it is noted that InFat is a trademark representing a fat composition or concentrate comprising a specific range of constituents, which is also being claimed by Applicant. Therefore, since the art teaches InFat, and Applicant discloses that the edible concentrate is InFat, a teaching of InFat in the art would necessarily comprise the specific fatty acid residues in amounts that would meet the claimed ranges or amounts,

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and therefore, such a teaching of InFat in the art anticipates, or in the alternative, renders obvious the claimed edible concentrate for the reasons as set forth above.

### ***Conclusion***

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

36. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jenna A. Watts whose telephone number is (571) 270-7368. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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39. Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/

Primary Examiner, Art Unit 1781

/Jenna A. Watts/

Examiner, Art Unit 1781

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